

PARTICIPANT INFORMATION SHEET

Name of Investigator:	Wendy Russell
Name of Study:	Black Barley

You are invited to take part in a research study. Before you decide whether to volunteer, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

Please do not hesitate to contact us (see below) if there is anything that is not clear or if you would like more information.

What is the purpose of this study?
There is lots of scientific evidence that eating wholegrain cereals such as barley can protect against disorders such as type 2 diabetes, obesity and cardiovascular disease. This may be due to a carbohydrate called beta-glucan, which has been shown to lower cholesterol. In this study we will look to see if a specifically bred barley, rich in beta-glucan and compounds called phytochemicals ("phyto" means "plant"), can also reduce glucose in your blood, which is another risk factor for type 2 diabetes and cardiovascular disease. The barley cereal we are studying may also be beneficial to the environment compared to other cereals grown in Scotland.

Who can take part?
<p>You can take part in this study if you are male or female (over 18 years) and have Diabetes Risk Score (defined by Diabetes UK) ≥ 7 points. We will calculate this score by taking into account your age, body mass index, waist circumference, gender, ethnicity, family history and blood pressure. The Score provides a likelihood of developing Type 2 Diabetes Mellitus in the next 10 years:</p> <p>0-6 points Low Risk (1 in 20 people will develop T2D in the next 10 years) 7-15 points Increased Risk (1 in 10 people will develop T2D in the next 10 years) 16-24 points Moderate Risk (1 in 7 people will develop T2D in the next 10 years) 25-47 points High Risk (1 in 3 people will develop T2D in the next 10 years)</p> <p>You cannot take part in this study if you have:</p> <ul style="list-style-type: none"> • Diabetes Risk Score below 7 points • Type 1 diabetes • Type 2 diabetes controlled with medication • Coeliac Disease • Eating disorders • Food allergies/intolerances • Any significant health issues

- Addiction to any substances
- Breastfeeding/ Pregnancy
- Are unable to give written informed consent

Do I have to take part?

No, it is up to you to decide if you would like to take part or not. You are also free to withdraw at any time, without giving a reason; it will not affect the standard of care you receive.

In the event of withdrawal, any data already collected will be archived with the rest of the study documents. Any anonymous data up until the point of withdrawal will be used in analysis if you have consented to this.

All of your personal information will be held in accordance with the Institute privacy policy <https://www.abdn.ac.uk/rowett/about/privacy-policy-1045.php> and all data will be managed according to the University data policy.

What will happen to the samples I provide?

All the samples will be coded to maintain confidentiality. Your samples may be kept for up to ten years after the study is completed. After this period we will destroy your samples.

What will happen to me if I take part?

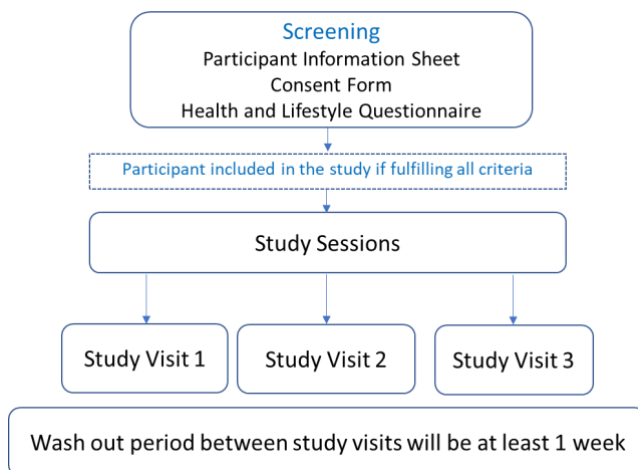
If you take part in the study all the information collected during the course of the study will be kept strictly confidential.

Screening

Once you have expressed interest to volunteer, we will be in touch with you to explain the study and give you the opportunity to ask any questions you may have. The eligibility for your participation will be assessed via completion of a health screening questionnaire. You can choose to complete the questionnaire in person at the Rowett Institute or from the comfort of your home and return it to us together with a consent to participate. If you fulfil all the criteria, see section “ Who can take part?”, you will be invited to take part in the study.

Your participation in the study will involve you coming for three Study Visits to the Human Nutrition Unit (HNU) at the Rowett Institute on days selected by you -see Figure 1 below.

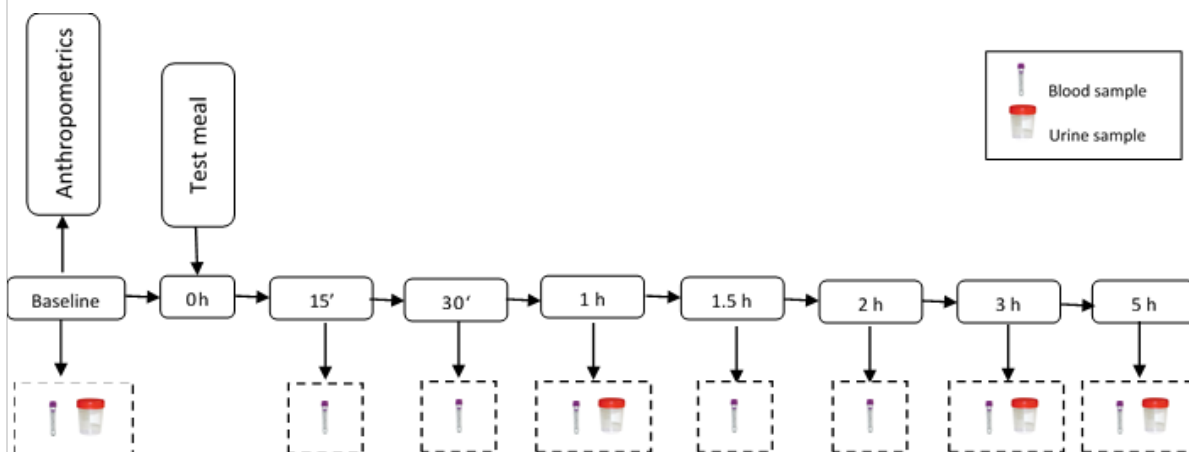
Figure 1.



Study Visits

During the Study Visits you will be asked to consume one of three types of test meals which will be a barley- or wheat-based bread products. The protocol for the Study Visits is illustrated in Figure 2 below.

Figure 2.



On the day of the Study Visit, you would have to attend the HNU in the morning in a fasted state (i.e. not having taken any food and drinks except water after 10 pm the previous evening). Upon your arrival, we will measure your height, weight and waist circumference (only at study visit 1) and will ask you to provide a urine sample. At study visit one only, we will also collect finger prick blood sample. We will then take repeated blood samples by inserting a thin flexible plastic tube known as a cannula into a blood vessel. This tube will remain for the duration of the experiment and will cause only minimal discomfort. Following first blood sample collection, we will invite you to consume the test meal, and we will collect blood samples at 15min, 30min, 1h, 1.5h, 2h, 3h and 5h post-meal consumption. The total amount of blood sampled will be approximately 4 tablespoons. At time-points 1h, 3h and 5h we will also collect a urine sample (see Figure 2). During the intervention, you will be asked to minimise your movement. On completion, you will be provided with a lunch and then you are free to leave the HNU. The period between visits to the Institute is known as the washout period. This time will allow any natural components that may have been taken up when you ate the experimental bread to be “washed out” of your body. Each study session will be followed by at least one-week washout period before crossing over to the second and third treatment.

Expenses and payments

We will refund your travel expenses up to £50 from home/work to the Rowett Institute on completion of the study.

What are the possible benefits of taking part in the study?

You will be greatly contributing to the scientific knowledge of the benefits of eating wholegrain cereals and helping to promote crops that could benefit the environment and develop the barley food sector on Scotland. If you wish, we will be happy to keep you informed regarding the outcomes of the study and also to provide you with a copy of any publications that may result from your participation in our study.

What are the possible disadvantages and risks of taking part in this study?

You will be required to give up your time for three visits to the Rowett Institute. There is a possibility that you may experience mild discomfort during blood sampling and some individuals may feel faint. All blood sampling will be performed by a trained member of staff, but you may experience some bruising in the immediate area.

What if there is a problem?

At any time during the study, if you have a complaint or a concern that you have been unable to resolve with the Principal Investigator or the Human Nutrition Unit Manager; Ms Sylvia Stephen (01224438607, sylvia.stephen@abdn.ac.uk), you may contact the Head of Human Studies Management Committee; Dr Frank Thies (+44 (0)1224 437954, f.thies@abdn.ac.uk). The Institute carries indemnity insurance for any harm or adverse event and Dr Frank Thies can be contacted for further information.

What if you find something in my samples?

If we find a blood test result that is out-with the normal range, we will inform you and your GP in writing.

Who has reviewed this study?

This study has been reviewed and approved by The Rowett Institute Ethical Panel.

Who is organising and funding the research?

This study is funded by the Scottish Governments Rural and Environmental Science and Analytical Services Division as part of its Strategic Research Program.

Will my taking part be kept confidential?

Your anonymity will be guaranteed in any internal report or conference presentation relating to this study. A confidential participant log will record details of names and addresses of participants. In all documentation (except the consent form) the participants will be identified by a code allocated to them in the participant log. All of the data will be held in locked cabinets, in locked offices and/or on password protected computers. All data will be stored for a maximum of 10 years, after which they will be destroyed.

CONTACTS FOR STUDY

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